JUL 1 9 2005 K050210

510(k) Summary

Applicant/Sponsor: Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person: Lonnie Witham
Telephone: (574) 267-6639
Fax: (574) 372-1683

Proprietary Name: Disposable Cement Spacer Molds for Temporary Knee Prosthesis

Common Name: Bone Cement Spacer Mold

Classification Name: Knee joint, patellofemorotibial, polymer/metal/polymer, semi-constrained, cemented prosthesis (21 CFR 888.3560)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: Spacer-K Temporary Knee Prosthesis cleared by the FDA in K032522 and marketed by Exactech, Inc., Gainesville, FL.

Device Description: The femoral cement spacer molds are offered in four sizes (60mm, 65mm, 70mm & 75mm). The tibial cement spacer molds are offered in four sizes (65mm, 70mm, 75mm & 80mm). The disposable cement spacer molds are not implanted. They are filled with polymethylmethacrylate /gentamicin bone cement, or equivalent, either by injecting with a dispenser/gun, or by pouring the prepared cement into the mold. After the cement hardens, the temporary knee prosthesis components are removed from the molds and placed into the joint space. The temporary knee prosthesis remains in place (180 days or less) until the second stage of the two-stage procedure is performed to implant a conventional knee joint prosthesis.

Intended Use: The intended use of the Biomet disposable cement spacer molds is to provide the surgeon with a means to mold a temporary knee prosthesis at the point of care that is substantially equivalent to the Exactech Spacer-k temporary knee prosthesis cleared in K032522. The temporary knee prosthesis made with the Biomet disposable cement spacer molds has the same indication for use as the Exactech Spacer-k.

Indication for Use: Disposable cement spacer molds are indicated for use to mold a temporary total knee replacement (TKR) for skeletally mature patients undergoing a two-stage procedure due to a septic process. The molded temporary knee prosthesis is indicated for an implantation period of 180 days or less. Because of inherent mechanical limitations of the device material (polymethylmethacrylate/gentamicin), the molded temporary prosthesis is only indicated for patients who will consistently use traditional mobility assist devices (e.g. crutches, walkers) throughout the implant period.

Contraindications:
The temporary knee prosthesis made with the disposable cement spacer molds is contraindicated for the following situations:

- The patient's condition is such that a two-stage arthroplasty procedure is contraindicated due to decreased immune response or other relevant systemic clinical conditions.
- Bone loss precluding adequate support of the prosthesis.
- Lack of adequate competence (anatomical and functional) of peripheral ligamentous apparatus and extensor mechanism.
- The procedure is unjustified due to deficiencies in the patient's muscular, nervous or vascular systems.
- Poor bone quality (as in osteoporosis) could cause the prosthesis to migrate or to fracture host bone.
- Infection of the TKR cannot be confirmed.
- The infected TKR devices cannot be removed.
- The infecting pathogens are resistant to gentamicin.
- The patient is sensitive (allergic) to gentamicin, aminoglycosides or PMMA bone cement.
- A systemic or secondary remote infection is expected or confirmed.
- The patient does not have a TKR and the infection is secondary to trauma, septic arthritis or other surgical procedures.
- The patient does not have sufficient bone stock to allow insertion and fixation of the prosthesis.
- The patient has neuromuscular disorders that do not allow control of the knee joint.
- The patient's age, weight, or activity level would cause the surgeon to expect early failure of the system.

Summary of Technologies: The bone cement molds (femoral and tibial) are sterile disposables made of medical grade silicone. The disposable cement spacer molds produce temporary knee prosthesis components that are composed of similar bone cement in similar sizes as the predicate.

Non-Clinical Testing: Comparative testing was performed utilizing a knee joint simulator on both the temporary knee prosthesis made with the Biomet disposable cement spacer molds and the Exactech Spacer-K device. The temporary knee prostheses were found to be equivalent in strength and wear characteristics. Elution testing demonstrated equivalent gentamicin release.

Clinical Testing: No clinical testing was performed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 9 2005

Mr. Lonnie Witham
Biomet, Inc.
56 East Bell Drive
Warsaw, Indiana 46581

Re: K050210
Trade/Device Name: Disposable Spacer Molds for Temporary Knee Prosthesis
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: June 30, 2005
Received: July 1, 2005

Dear Mr. Witham:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

Miriam C. Provost, Ph.D
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

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Prescription Use YES (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-USE ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

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